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SC Department of Labor, Licensing, & Regulation – Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Board Elections

At the June 2006 meeting, the South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy members elected Marvin A. Hyatt, Sr, RPh, as its new chairman. Mr Hyatt is the pharmacist representative serving the Fifth Congressional District. Dock Henry Rose, RPh, representing the Fourth Congressional District, was elected as vice-chairman. Each will serve a one-year term from July 1, 2006 until June 30, 2007.

Citations and Notice of Penalty

At its March 15, 2006 Board of Pharmacy meeting, the Board voted unanimously to allow pharmacist inspectors to issue citations and notification of penalty for the following alleged violations of the South Carolina Pharmacy Practice Act:

§40-43-83(F)	Failure to Display Facility Permit	\$500
Regulations Chapter 99-15	Failure to Display Pharmacist License	\$100
§40-43-84(B)	Failure to Display Intern Certificate	\$25
§40-43-82-(A)(3)	Failure to Display Pharmacy Technician Registration	\$25
§40-43-83(D)	Allowing Non-registered Pharmacy Technician to Practice (Permit Holder)	\$500
§40-43-86(B)(3)(a) §40-43-83(D)	Allowing Non-registered Pharmacy Technician to Practice (Pharmacist-in-Charge)	\$500
§40-43-83(D)	Allowing practice with a lapsed Pharmacy Technician Registration (Permit Holder)	\$500
§40-43-86(B)(3)(a) §40-43-83(D)	Allowing practice with a lapsed Pharmacy Technician Registration (Pharmacist-in-Charge)	\$500
§40-43-82(A)(2)	Practicing with a lapsed Pharmacy Technician Registration (Pharmacy Technician)	\$50

§40-43-83(D)	Failure of Permit Holder to assure compliance with Technician to Pharmacist Ratio	\$500
§40-43-86 (B) (4) (b)	Failure of Pharmacist-in-Charge to assure compliance with Technician to Pharmacist Ratio	\$500
§40-43-83(D) §40-43-86 (B)(3)(b)(iii)	Failure of Permit Holder to notify SCBOP of Facility Relocation	\$500
§40-43-83(A) §40-43-83(B) §40-43-83(I)	Operating a Facility without a current Permit or with a Lapsed Permit (Permit Holder)	\$500

The penalty(ies) proposed is based on the violation(s) listed on the citation. You must pay the proposed penalty(ies) within thirty (30) days of receipt of this citation. You must correct the violations(s) referred to in the citation within thirty (30) calendar days from your receipt of this citation.

Citations and penalties may be protested by requesting, in writing, a panel hearing. Such requests must be mailed within thirty (30) calendar days from receipt of this citation to the Administrator, South Carolina Board of Pharmacy, PO Box 11927, Columbia, SC 29211-1927. **Failure to make a timely request for a panel hearing will result in the citation becoming a final order once approved by the Board at their next scheduled meeting. These documents are classified by the Freedom of Information Act as being public documents and will be posted on our Web site, www.llr.state.sc.us/pol/pharmacy.**

Board Policy on Citation Hearings

At its June 21-22, 2006 Board of Pharmacy meeting, the Board established the following policies on citations and panel hearings.

Policy and Procedure 143 – Only the individual for whom the citation was issued may appear before the hearing panel unless otherwise approved by the

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Generic Substitution Issues

This is a reminder to pharmacists regarding the legal generic substitution of certain drug products. Recent practices by pharmaceutical manufacturers involving the reformulation of drugs into alternative dosage forms (eg, tablets to capsules) seem to have caused some confusion.

Generic substitution is the act of dispensing a different brand or unbranded drug product than the one prescribed. Generic substitution is only allowable when the substituted product is therapeutically equivalent to the prescribed innovator product. Generic drug manufacturers must provide evidence to Food and Drug Administration (FDA) of therapeutic equivalence, which means that both products are pharmaceutically equivalent (eg, have the same active ingredients in the same dosage form and strength, and use the same route of administration) and bioequivalent (eg, have more or less the same rate and extent of absorption). Therapeutically equivalent drugs are expected to produce the same clinical benefits when administered for the conditions approved in the product labeling.

FDA assigns two-letter therapeutic equivalence codes to generic products when the products meet both the aforementioned requirements, are approved as safe and effective, are adequately labeled, and are manufactured in compliance with current Good Manufacturing Practice regulations. The primary reference guide for pharmacists on therapeutic equivalence is FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book." Drug products determined to be therapeutically equivalent to innovator drugs are assigned an "A" for the initial letter of their therapeutic equivalence code. The second letter provides additional information regarding the product: products rated AA, AN, AO, AP, or AT are those with no known or suspected bioequivalence problems (rating depends on dosage form). An AB rated product indicates that actual or potential bioequivalence problems have been resolved with adequate in vivo and/or in vitro evidence. In contrast, drugs assigned a "B" for the initial letter are not considered therapeutically equivalent because bioequivalence problems have not been resolved to the satisfaction of FDA.

A recent example of improper substitution has been brought to the attention of several boards of pharmacy by Acorda Therapeutics, the maker of Zanaflex[®] tablets, who recently released Zanaflex Capsules[™] (tizanidine hydrochloride). Although the active ingredient in Zanaflex Capsules is the same as the active ingredient in Zanaflex tablets and generic tizanidine tablets, their formulations are different. For this reason, FDA has deemed there to be no therapeutic equivalent to Zanaflex Capsules and has not assigned a therapeutic equivalence code.

A similar situation existed in 1995 when the manufacturer of Sandimmune[®] (cyclosporine) capsules and oral solution, Sandoz, (now Novartis), came out with NEORAL[®] (cyclosporine) capsules and oral solution for microemulsion. Due to differences in bioavailability, Sandimmune and Neoral, and their accompanying generic versions, were not, and still are not, rated as substitutable.

It must be emphasized that generic substitution mandates are found in individual state laws and regulations. In states where generic substitution is allowed only for "Orange Book" A-rated

products, pharmacists may not substitute a generic product for a non-A-rated product. Some states may have developed their own generic substitution lists or formularies. Pharmacists are encouraged to review the laws and regulations in their states to determine the appropriate legal methods by which to perform generic substitution.

Preventing Errors Linked to Name Confusion



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

The Institute for Safe Medication Practices (ISMP) regularly hears about confusion between products with similar names. One such pair is OMACOR (omega-3-acid ethyl esters) and AMICAR (aminocaproic acid) an antifibrinolytic. Omacor is indicated as an adjunct to diet to reduce very high triglyceride levels (500 mg/dL or more) in adult patients. The drug is also being studied as adjuvant therapy for the prevention of further heart attacks in patients who have survived at least one. A pharmacist reported an error in which a telephone order for Omacor 1 gram BID was interpreted and dispensed as Amicar 1 gram BID. Counseling was not provided, but fortunately the patient read the drug information sheet for Amicar before taking any medication and called the pharmacy stating that he was expecting a medication to reduce his triglyceride levels.

While this case illustrates why manufacturers should review and test new trademarks for error potential before the product reaches the market, there are some things that practitioners can do to help prevent errors with products that have look-alike or sound-alike names.

- ◆ Look for the possibility of name confusion before a product is used. Use the concepts of failure mode and effects analysis (FMEA) to assess the potential for error with new medications that will be prescribed or added to your inventory. If the potential for confusion with other products is identified, take the steps listed below to help avoid errors.
- ◆ Prescriptions should clearly specify the drug name, dosage form, strength, complete directions, as well as its indication. Most products with look- or sound-alike names are used for different purposes. If the indication is not available, pharmacists and nurses should verify the purpose of the medication with the patient, caregiver, or physician before it is dispensed or administered.
- ◆ Reduce the potential for confusion with name pairs known to be problematic by including both the brand and generic name on prescriptions, computer order entry screens, prescription labels, and MARs.



- ◆ When accepting verbal or telephone orders, require staff to write down the order and then perform a read back (or even spell back) of the medication name, strength, dose, and frequency of administration for verification.
- ◆ Change the appearance of look-alike product names on computer screens, pharmacy product labels, and MARs by emphasizing, through bold face, color, and/or tall man letters, the parts of the names that are different (eg, hydrOXYzine, hydrALAzine).
- ◆ Pharmacists should work under good lighting and use magnifying lenses and copyholders (keep prescriptions at eye level during transcription) to improve the likelihood of proper interpretation of look-alike product names.
- ◆ Install computerized reminders for the most commonly confused name pairs at your site so that an alert is generated when entering prescriptions for either drug. If possible, make the reminder auditory as well as visual.
- ◆ Store commonly confused products in different locations. Avoid storing both products in a "fast-mover area." Use a shelf sticker to help find relocated products.
- ◆ Affix "name alert" stickers to areas where look- or sound-alike products are stored (available from pharmacy label manufacturers) or to the actual product containers.
- ◆ Employ at least two independent checks in the dispensing process (one person interprets and enters the prescription into the computer and another compares the printed label with the original prescription as well as the manufacturer's product).
- ◆ Open the prescription bottle or package in front of the patient to confirm the expected appearance of the medication and review the indication. Caution patients about error potential when taking a product that has a look- or sound-alike counterpart. Encourage patients to ask questions if the appearance of their medication changes. Take time to fully investigate any patient concerns.
- ◆ Encourage reporting of errors and potentially hazardous conditions with look- and sound-alike names to the ISMP-USP Medication Errors Reporting Program and use the information to establish priorities, as listed above, for error reduction. Maintain an awareness of problematic product names and error prevention recommendations provided by ISMP (www.ismp.org), FDA (www.fda.gov), and USP (www.usp.org).

If you are interested in learning what look-alike and sound-alike name pairs have been published in the ISMP Medication Safety Alert!®, a free list is available at www.ismp.org/Tools/confuseddrugnames.pdf.

Combat Methamphetamine Epidemic Act Phasing In

This year, new requirements of the federal Combat Methamphetamine Epidemic Act passed by Congress for the sale of all single and multi-ingredient pseudoephedrine and ephedrine-containing products will become effective. The new law places non-prescription ephedrine, pseudoephedrine, and phenylpropanolamine in a new Controlled Substances Act category of "scheduled listed chemical products." Drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine are subject to sales restrictions, storage requirements, and record keeping requirements.

A 3.6-grams-per-day base product sales limit, 9-grams-per-30-days base product purchase limit, a blister package requirement, and mail-order restrictions went into effect on April 8, 2006,

for all sellers of these products. All other provisions of the law require compliance by September 30, 2006. If a state has more stringent requirements, the stronger requirements remain in place. A summary of this Act's requirements can be found on the United States Drug Enforcement Administration's (DEA) Web site at www.dea diversion.usdoj.gov/meth/cma2005.htm.

Explanation of DEA Regulations on Partial Refilling of Prescriptions

Pharmacists often question the DEA rule regarding the partial refilling of Schedule III, IV, and V prescriptions as stated in Section 1306.23 of the Code of Federal Regulations. Confusion lies in whether or not a partial fill or refill is considered one fill or refill, or if the prescription can be dispensed any number of times until the total quantity prescribed is met or six months has passed. According to DEA's interpretation, as long as the total quantity dispensed meets the total quantity prescribed with the refills and they are dispensed within the six-month period the number of times it is refilled is irrelevant. The DEA rule is printed below:

Section 1306.23 Partial Filling of Prescriptions.

The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible provided that:

- (a) Each partial filling is recorded in the same manner as a refilling,
- (b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and
- (c) No dispensing occurs after 6 months after the date on which the prescription was issued.

[21 CFR 1306.23]

Electronic Version of DEA Form 106 Now Available

DEA has announced that a secure, electronic version of the DEA Form 106 (Report of Theft or Loss of Controlled Substances) is now available to DEA registrants. The electronic form may now be completed online through a secure connection and submitted via the Internet to DEA Headquarters. Copies of the letter from DEA and the 2005 Final Rule were published in the *Federal Register*. The new interactive form is located at the Diversion Control Program's Web site and may be accessed at www.DEAdiversion.usdoj.gov.

Patients Rely on Pharmacists' Recommendations

Patients consider their pharmacists a trusted source for medication recommendations, as evidenced by the result of a poll recently conducted by the American Pharmacists Association (APhA). APhA polled 3,000 community pharmacists and found that pharmacists were asked about over-the-counter (OTC) products an average of 32 times each week. Of those pharmacists surveyed, 55% said they spend three to five minutes with each patient who asks about an OTC. And patients are listening, for during this consultation time, according to the survey, 81% of patients purchased OTC products recommended by the pharmacist.

The results of the poll was published in APhA's *Pharmacy Today*. Other topics researched in the poll include recommendation habits of pharmacists in leading OTC therapeutic areas including treatments for allergies, adult cold symptoms, adult headache remedies, heartburn, pain relief, and tooth whitening products among others.

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administrator. The individual for whom the citation was issued may designate someone to appear on their behalf in writing within ten (10) days of the hearing.

Terms of payment of civil penalties will be established by the hearing officer at the time of the hearing.

The hearing officer will publish and document on the record acknowledgement by the respondent the timeframe for filing of a formal appeal (30 days).

Tips from the Compliance Department

The Board of Pharmacy's inspectors would like to make the following recommendations to ensure compliance with the laws and regulations that govern the practice of pharmacy.

- ◆ As a reminder to the pharmacists, the date a telephoned prescription is called-in **must** be recorded when the prescription is reduced to writing.
- ◆ There must be a pharmacist on-site during all business hours, including periods when the pharmacist takes a break. In such circumstances, a pharmacist must remain in the building during the break. Otherwise, the closed sign must be posted and the pharmacy technicians must leave the area.
- ◆ As a reminder, state certified pharmacy technicians **cannot** work alone in the pharmacy.
- ◆ If you have any questions regarding controlled substances, please contact the Bureau of Drug Control at 803/896-0636.
- ◆ A student from high school, college, or technical college is allowed to shadow in pharmacies at the discretion of the pharmacist-in-charge (PIC). However, if the PIC allows this to occur, the student does not have to be registered as a pharmacy technician provided he or she is **only observing**.

The Board of Pharmacy staff would like to thank you for your courtesy and cooperation during and after inspections. If you have any questions regarding these or any other compliance issues, please contact the Board office at 803/896-4700.

Policy and Procedure No. 66 – Prescription Format, Integrity of Prescription, and Electronic Prescriptions

The practitioner is responsible for the integrity of the prescription. The pharmacist must use his or her professional judgment in accepting and may refuse or check with the practitioner if any doubt exists regarding the prescription's validity.

Prescriptions received by a pharmacist from a patient must have (a) an original signature of a practitioner or (b) a digital signature and be printed on paper that supplies security features preventing duplication or modification.

Electronic signatures are only permissible on prescriptions sent directly from a practitioner to a pharmacy via electronic transfer and cannot be modified in any way.

Rubber stamped signatures are not acceptable.

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